

Appl. No. 10/828,531
Amdt. dated April 18, 2007
Reply to Office action of February 14, 2007

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include changes to FIG. 1. The first sheet replaces the originally filed FIG. 1. The second sheet is an annotated sheet illustrating the changes made.

REMARKS/ARGUMENTS

I. Disposition of Claims

Claims 1-26 are pending in the subject application. Claims 22-26 have been withdrawn from consideration as non-elected claims in a previous amendment. Claims 1-21 stand presently rejected.

II. General Comments

The Applicants express their appreciation for the Examiner's thorough review of the subject application and his well drafted Office action dated February 14, 2007 (hereinafter referred to as the "Office action").

III. Objections to Disclosure

The Applicants are proposing the amendment of FIG. 1 in this paper to include a designation by a legend, specifically the use of "(Prior Art)," as recommended by the Examiner in the Office action.

IV. Objections to the Claims

Claim 14 was objected to in the Office action as being of improper form for failing to indent each recited element of the subject kit. Claim 14 is amended in this paper to include indentations.

Claim 20 was objected to in the Office action as being of improper dependent form for failing to further limit the subject matter of the previous claim (Claim 14). Claim 14 has been amended to remove the redundant language as compared to Claim 20. Therefore, the Applicants invite the Examiner to re-consider Claim 20 for proper dependent form.

V. Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 1-21 currently stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. In response to these rejections, the Applicants argue as follows:

First, M.P.E.P. §2173.01 provides that an Applicant is his own lexicographer or specifically:

“A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as **>any special meaning assigned to a term is clearly set forth in the specification.”

Second, M.P.E.P. §2173.04 provides that the breadth of a claim is not to be equated with indefiniteness or specifically:

“Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.”

The Applicants respectfully traverse the Examiner's §112, second paragraph rejections.

With the above guiding principles in mind, the Applicants will now address the Examiner's specific §112, second paragraph rejections.

V.1 Claims 1, 11-14, and 21--"Corresponding to"

The Examiner argued in the Office action that the term "corresponding to" is not an art-recognized term and does not establish the requisite metes and bounds of the subject claims. The Applicants have amended paragraph [0029] in the Specification to include an explicit relationship between the term "corresponding to," which was used in the Claims as originally filed, and the substantive description of the term "corresponding to," which was provided in the Specification as originally filed. The purpose of this amendment to the Specification is to provide an explicit nexus between the term "corresponding to" and its substantive description. Since an Applicant can be his own lexicographer and the breadth of a claim is not equated with indefiniteness (as long as there is an understanding of the claim's scope as defined in the Specification), the Applicants invite the Examiner to evaluate the amendment to paragraph [0029] as well as review paragraphs [0030] through [0032], including the table on page 15 of the Specification. The Applicants argue that the metes and bounds of the term "corresponding to" are now explicitly defined such that the Examiner's §112, second paragraph rejection is hereby respectfully traversed based on the amendments to the Specification. The Applicants have disclosed the importance of the hydropathic index of

amino acids in conferring biological function on a peptide. Further, the Applicants have proposed that biological functional equivalence may typically be maintained where amino acids are exchanged having no more than a ± 1 to 2 difference in the index value, and more preferably within a ± 1 difference. The Applicants go further to provide tables of amino acids and their hydropathic index as well as exemplary substitutions based on the index values and relative differences. Notwithstanding the above arguments, the Applicants have amended Claims 13-17 and 19 whereby the term “identical to” is used. In no way are these amendments intended to narrow the metes and bounds of the term “corresponding to.” The Applicants invite the Examiner to re-consider all of the subject claims in light of the amendments to the Specification and the Claims.

V.2 Claims 1, 11-14, and 21--Omission of Essential Structural Cooperative Language

The Examiner argued in the Office action that the subject claims are incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. The Applicants have amended all of the subject claims such that the language, “determining total urokinase concentration in said sample by determining the quantity of each of said immunological compositions that is bound to at least one of said forms of urokinase” or its equivalent is now included and identified as a method step. The Applicants invite the Examiner to re-consider the subject claims in light of these amendments.

V.3 Claims 6-7 and 18-19--Omission of Essential Structural Cooperative Language

The Examiner argued in the Office action that the subject claims are incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. The Applicants respectfully point out that Claims 6-7 should be Claims 7-8. The Applicants have amended Claims 7-8 such that the subject method further comprises an additional step of obtaining a fourth peptide rather than a “wherein” statement directed to “an additional peptide.” The Applicants have amended Claim 19 wherein the subject kit’s peptide is further comprised of a fourth peptide rather than “an additional [peptide].” Claim 18 is cancelled in this paper. The Applicants invite the Examiner to re-consider the subject claims in light of these amendments.

V.4 Claims 6, 11-13 and 21--Reference to Urokinase Zymogen

The Examiner argued in the Office action that the Applicants’ reference to urokinase zymogen is unclear because one does not know how this reference relates to the “active and inactive forms of urokinase.” The Applicants respectively argue that urokinase zymogen is commonly known in the art to be an inactive form of urokinase. Further, the Applicants point the Examiner to paragraph [0010] in the Specification of the subject case, wherein the inactive form of urokinase zymogen and how it’s activated is clearly described. For clarity purposes, the reference to urokinase zymogen in the subject claims has been amended such that the language, “an inactive form of urokinase,” has

been added. The Applicants invite the Examiner to re-consider Claims 6, 11-13, and 21 in light of this amendment and the remarks herein this paragraph.

V.5 Claims 6-7 and 14--“Used to Derive” is Unclear

The Examiner argued in the Office action that the use of the term “used to derive” is unclear because base Claims 1 and 14 have recited “obtaining” not “deriving” immunological compositions. The Applicants respectfully point out that the word “derive” and its derivatives is included in Claims 5-7 (not just 6-7) and 18 (not 14). All derivatives of the word “derive” have been deleted. The Applicants invite the Examiner to re-consider Claims 5-7 and 18 in light of these amendments.

V.6 Claims 11-13 and 21--“Determining the Amount”

The Examiner argued in the Office action that the term “determining the amount” in the last three paragraphs are not consistent with the recitation in the preceding paragraph of a “quantity” rather than an “amount.” The Applicants respectfully point out that the word “quantity” relates to an immunological composition as opposed to the word “amount,” which relates to urokinase concentration. As contained in the Specification, the urokinase concentration is determined by a correlation to the quantity of immunological compositions that is bound to at least one form of urokinase in each of said aliquots. The Examiner is invited to re-consider the subject claims in light of this explanation.

V.7 Claim 14--“A Peptide Directed Against a Set of Peptides”

The Examiner argued in the Office action that in the “said immunological compositions” paragraph, the recitation of “a peptide directed against each of a set of peptides” is unclear. Claim 14 is amended in this paper. The Applicants invite the Examiner to re-consider Claim 14 in light of the amendment in this paper.

V.8 Claim 18--“Seq. ID No. 15 is Unclear”

The Examiner argued in the Office action that Claim 18’s reference to “Seq. ID No. 15 which includes amino acid residues 135 and 136” is unclear because “Seq. ID No. 15” has only 10 amino acid residues. Claim 18 has been cancelled in this paper.

VI. Rejections Under 35 U.S.C. 112, First Paragraph

The Applicants respectfully traverse the Examiner’s §112, first paragraph rejections based on the following arguments.

VI.1 Claims 9 and 13-20--“Immunological Composition is a Hybridoma”

The Examiner argued in the Office action that a hybridoma is not an immunological composition (aka an antibody), but rather, a hybridoma secretes antibodies. The Applicants have amended the subject claims to remove the references to a hybridoma. The Applicants invite the Examiner to re-consider the subject claims in light of this amendment.

VI.2 Claims 1-21--“Genus of Immunological Compositions and Inaccurate Reference to Hybridoma”

The Examiner argued in the Office action that the Applicants have not adequately described the genus of “immunological compositions” because of an inaccurate reference to hybridoma as an immunological composition. The Examiner stated that since the Applicants have listed a member that is an improper member of the genus “immunological composition,” one cannot picture what else the genus includes. The subject claims have been amended such that “hybridoma” is not referenced as a member of the genus “immunological composition.” The Applicants invite the Examiner to re-consider all claims based on these amendments.

VI.3 Claims 1-21--“Corresponding to”

As discussed *supra*, the Applicants have amended the Specification to provide an explicit nexus between the term “corresponding to” and its substantive description. The Applicants invite the Examiner to re-consider the subject rejection based on a re-evaluation of paragraphs [0030] through [0032], including the table on page 15 of the Specification. The Applicants have disclosed the importance of the hydropathic index of amino acids in conferring biological function on a peptide. Further, the Applicants have proposed that biological functional equivalence may typically be maintained where amino acids are exchanged having no more than a ± 1 to 2 difference in the index value, and more preferably within a ± 1 difference. The Applicants go further to provide tables

of amino acids and their hydropathic index as well as exemplary substitutions based on the index values and relative differences. Notwithstanding the above arguments, the Applicants have amended Claims 13-17 and 19 whereby the term “identical to” is used. In no way are these amendments intended to narrow the metes and bounds of the term “corresponding to.” Claim 18 is cancelled in this paper. The Applicants invite the Examiner to re-consider all of the subject claims in light of the amendments to the Specification and the Claims.

VII. Miscellaneous Amendments

The following amendments are made in this paper:

Claims 1 and 13 -- The first three steps in Claims 1 and 13 were combined into a single step of obtaining at least one peptide comprised of a first, second, or third peptide, or any combination.

Claims 2-4 -- To ensure definitiveness and consistency, the term “as in any” has been replaced with the term “corresponds to.”

Claim 6 -- To ensure definitiveness, the term “one as in” has been replaced with the term “identical to.” Since “identical to” is narrower than the term “corresponds to” and Seq. No. ID 14 further limits the term “Seq. ID No. 16 which includes amino acid residues 158 and 159,” the term “identical to” is proper in this dependent claim.

Claim 7-- For clerical purposes, the language “a sequence in” and “is obtained and used to derive said immunological composition” have been deleted. The aforementioned language is superfluous and adds no substance to the claim.

Claim 11-- To ensure proper antecedent basis, the “peptides” referenced in the claim have been appropriately identified using the following identifiers: “first,” “second,” and “third” peptides, which are defined in Claim 1, wherein Claim 11 is dependent on.

Claim 12-- To ensure proper antecedent basis and definitiveness, the claim has been amended to further comprise a “fourth” peptide and other referenced “peptides” have been appropriately identified using the following identifiers: “first,” “second,” and “third” peptides, which are defined in Claim 1, wherein Claim 12 is dependent on.

Claim 13-- To ensure proper antecedent basis, a restructuring of the claim language is proposed. As written, the claim did not have proper antecedent basis for some of the claim elements. For example, in the claim, “a peptide” has at least three possible definitions. Hence, the following identifiers are proposed: “first,” “second,” and “third” peptides. As another example, Seq. ID Nos. 1-6 was defined and later further limited by the language “Seq. ID No. 16 between amino acid residues 1 and 135.” However, even if one combined Seq. ID Nos. 1-6, the entire range of amino acid residues between 1 and 135 is not fully covered. Therefore, “Seq. ID No. 16 between amino acid residues 1 and 135” does not further limit “Seq. ID Nos. 1-6.” But, “Seq. ID Nos. 1-6” does further limit “Seq. ID No. 16 between amino acid residues 1 and 135.” Various amendments are proposed to correct the antecedent-basis deficiencies.

Claim 14 -- Further, Claim 14 has been amended such that the previous second "element" beginning with the language "said immunological compositions" was combined with the first element of the claim. The previous second element is better suited for a "wherein" limitation as opposed to a separate element in a claim. In addition, Claim 14 now incorporates indentions for clarification purposes relative to what at least one peptide is comprised of.

Claim 19 -- For proper antecedent basis, the term "an additional" has been replaced with the following language: "peptide is further comprised of a fourth peptide identical to." The fourth peptide is identical to Seq. ID No. 17, which is identical to Seq. ID No. 16 between amino acid residues 132 and 138. It is noted that the previous language (now deleted in this paper) in Claim 18 that referenced amino acid residues 135 and 136 would have been appropriate in Claim 19.

Claim 21 -- For consistency purposes, the term "as in" has been replaced with the term "corresponding to." Further, a restructuring of the claim language similar to amended Claim 13, discussed *supra*, is proposed.

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IV. Conclusion

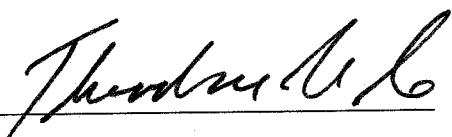
The Applicants submit that this paper is fully responsive to the Office action and that all claims stand in a condition for allowance.

The Commissioner is hereby authorized to charge any fee which may be required, or credit any overpayment, to Deposit Account No. 14-0116.

Respectfully submitted,

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By



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